

AMENDMENT TO THE CLAIMS

Please amend claims 1, 20, and 49-51.

Please add new claims 56-60.

1. (Currently Amended) A computer-implemented method for the identification of a drug target associated with a selected biological condition, comprising:

using a computer to analyze stored data related to medical histories of a population;

using a computer to analyze stored data related to medical test results for the population; and

based on computer analysis of the data related to the medical histories and the data related to the medical test results, classifying the population into at least two phenotypic sub-populations defined as

at risk and affected (ARA), whose members have ever been affected by the selected biological condition, and

at risk and unaffected (ARU), whose members ought to be affected by the selected biological condition at the present time based on a risk analysis, but are unaffected by the selected biological condition at the present time;

performing a computer analysis of genetic data from the ARA sub-population and the ARU sub-population to identify genetic variations therebetween; and

using data related to the identified genetic variations between the ARA sub-population and the ARU sub-population to identify the drug target associated with the selected biological condition.

2. (Original) The method of claim 1, further comprising generating statistical data related to the medical histories and the medical test results wherein classifying the population comprises analyzing the statistical data.

3. (Original) The method of claim 1 wherein analyzing medical histories comprises assigning numerical scores to selected conditions associated with the selected biological condition.

4. (Original) The method of claim 1 wherein analyzing medical test results comprises assigning numerical scores to selected medical tests associated with the selected biological condition.

5. (Original) The method of claim 1 wherein analyzing medical histories and medical test results comprises assigning numerical scores to selected conditions associated with the selected biological condition and analyzing medical test results comprises assigning numerical scores to selected medical tests associated with the selected biological condition.

6. (Original) The method of claim 5 wherein classifying the population comprises evaluating the numerical scores for the medical histories and the medical test results.

7. (Original) The method of claim 6 wherein classifying the population comprises combining the numerical scores for the medical histories and the medical test results and classifying the population based on the combined numerical scores.

8. (Original) The method of claim 5, further comprising generating statistical data related to the numerical scores for the medical histories and the medical test results wherein classifying the population comprises analyzing the statistical data.

9. (Original) The method of claim 8 wherein the statistical data comprises generating a frequency distribution plot related to the numerical scores for the medical histories and the medical test results.

10. (Original) The method of claim 1, further comprising comparing the medical histories and the medical test results of the sub-population classified as *ARU* with the medical histories and the medical test results of the sub-population classified as *ARA*.

11-13. (Canceled)

14. (Original) The method of claim 1, further comprising selecting the portion of the sub-population classified as *ARA* and using the selected portion as a control group.

15. (Previously Presented) The method of claim 1 wherein classifying the population further comprises classifying the population into the *ARA* sub-population, the *ARU* sub-population or a phenotypic sub-population defined as unknown risk and unaffected (*URU*) by the selected biological condition.

16. (Original) The method of claim 15, further comprising comparing the medical histories and the medical test results of the sub-population classified as *ARU* with the medical histories and the medical test results of the sub-population classified as *URU*.

17. (Original) The method of claim 15 wherein the medical test results comprises genetic test results, the method further comprising comparing the genetic test results of the sub-population classified as *ARU* with the genetic test results of the sub-population classified as *URU*.

18. (Original) The method of claim 17, further comprising determining genetic differences between genetic test results of the sub-population classified as *ARU* with the genetic test results of the sub-population classified as *URU*.

19. (Previously Presented) The method of claim 18, further comprising identifying drug targets based on the genetic differences between genetic test results of the sub-population classified as *ARU* with the genetic test results of the sub-population classified as *URU*.

20. (Currently Amended) A computer-implemented method of data analysis to identify a target for use in treating a selected biological condition, comprising:

defining disease characteristics of the selected biological condition, including medical tests associated with the selected biological condition;

performing a computer analysis of medical test results based on medical tests performed on biological samples from a plurality of subjects with respect to the defined characteristics of the selected biological condition;

based on the analysis, determining an affected status of each of the plurality of subjects;

defining risk characteristics of the selected biological condition;

based on the risk characteristics, determining a risk status of each of the plurality of subjects;

based on the affected status and the risk status, classifying each of the plurality of subjects into a predetermined category for the selected biological condition selected from a group comprising at risk, affected (ARA), whose members have ever been affected by the selected biological condition, and at risk, unaffected (ARU), whose members remain unaffected by the selected biological condition and whose unaffected status is inconsistent with the risk status;

performing genetic ~~testes~~tests on the plurality of subjects;

analyzing the genetic test results of the group of subjects classified as ARU with the genetic test results of the group of subjects classified as ARA to determine genetic differences between genetic test results of the group of subjects

classified as ARU with the genetic test results of the group of subjects classified as ARA; and

identifying one or more targets for use in treating the selected biological condition.

21. (Original) The method of claim 20 wherein the defined disease characteristics of the selected biological condition have associated numerical scores and determining the affected status of each of the plurality of subjects comprises determining numerical scores based on the analysis of the medical test results.

22. (Original) The method of claim 20 wherein the defined risk characteristics of the selected biological condition have associated numerical scores and determining the risk status of each of the plurality of subjects comprises determining numerical scores.

23. (Original) The method of claim 20 wherein the defined disease characteristics of the selected biological condition have associated numerical scores and the defined risk characteristics of the selected biological condition have associated numerical scores, the classification of each of the plurality of subjects into a predetermined category being based on the numerical scores for affected status and risk status.

24. (Original) The method of claim 23 wherein the numerical scores for affected status and risk status are combined to form a combined numerical score, the classification of each of the plurality of subjects into a predetermined category being based on the combined numerical scores for affected status and risk status.

25. (Original) The method of claim 20 wherein the medical tests associated with the selected biological condition have varying degrees of relevance in

defining the disease characteristics, the method further comprising assigning relevance weighting factors to the medical tests based on the degree of relevance, the affected status being based on the weighted medical tests.

26. (Original) The method of claim 20, further comprising generating statistical data related to the affected status and risk status wherein classifying each of the plurality of subjects into a predetermined category comprises analyzing the statistical data.

27. (Canceled)

28. (Previously Presented) The method of claim 20 wherein risk status is determined at least in part from medical histories of the plurality of subjects, the method further comprising comparing the medical histories and the medical test results of the group of subjects classified as *ARU* with the medical histories and the medical test results of the group of subjects classified as *ARA*.

29-30. (Canceled)

31. (Previously Presented) The method of claim 20 wherein identifying one or more targets comprises identifying a drug target based on the genetic differences between genetic test results of the group of subjects classified as *ARU* with the genetic test results of the group of subjects classified as *ARA*.

32. (Previously Presented) The method of claim 20 wherein identifying one or more targets comprises identifying a diagnostic assay based on the genetic differences between genetic test results of the group of subjects classified as *ARU* with the genetic test results of the group of subjects classified as *ARA*.

33. (Currently Amended) The method of claim 20 wherein identifying one or more targets comprises identifying a vaccine component based on the genetic differences between genetic test results of the group of subjects classified as *ARU* with the genetic test results of the group of subjects classified as *ARA*.

34. (Original) The method of claim 20 wherein the plurality of subjects are classified into a category selected from a group comprising at-risk, affected (*ARA*), unknown risk, unaffected (*URU*), and at risk unaffected (*ARU*).

35. (Original) The method of claim 34 wherein risk status is determined at least in part from medical histories of the plurality of subjects, the method further comprising comparing the medical histories and the medical test results of the group of subjects classified as *ARU* with the medical histories and the medical test results of the group of subjects classified as *URU*.

36. (Original) The method of claim 34 wherein the medical test results comprises genetic test results, the method further comprising comparing the genetic test results of the group of subjects classified as *ARU* with the genetic test results of the group of subjects classified as *URU*.

37. (Original) The method of claim 36, further comprising determining genetic differences between genetic test results of the group of subjects classified as *ARU* with the genetic test results of the group of subjects classified as *URU*.

38. (Previously Presented) The method of claim 37, further comprising identifying a drug target based on the genetic differences between genetic test results of the group of subjects classified as *ARU* with the genetic test results of the group of subjects classified as *URU*.

39. (Original) The method of claim 38, further comprising identifying a diagnostic assay based on the genetic differences between genetic test results of the group of subjects classified as *ARU* with the genetic test results of the group of subjects classified as *URU*.

40. (Currently Amended) The method of claim 38, further comprising identifying a vaccine component based on the genetic differences between genetic test results of the group of subjects classified as *ARU* with the genetic test results of the group of subjects classified as *URU*.

41. (Previously Presented) A system for data analysis to identify a target for treating a selected biological condition, comprising:

a affected status data structure containing numerical data defining disease characteristics of the selected biological condition, including medical tests associated with the selected biological condition;

a disease risk data structure containing numerical data defining disease risk characteristics of the selected biological condition; and

a processor to:

accept medical test results from a plurality of subjects and assign affected status numeric scores to the medical test results based on the numerical data defining disease characteristics of the selected biological condition;

store the affected status numeric scores for each of the subjects in the affected status data structure;

accept medical history data from a plurality of subjects and assign current disease risk numeric scores to the medical history data based on the numerical data defining disease risk characteristics of the selected biological condition;

store the disease risk numeric scores for each of the subjects in the disease risk data structure;

determine an affected status and risk status for each of the subjects based on the respective affected status numeric scores and the current disease risk numeric scores;

based on the affected status and the risk status, classify each of the plurality of subjects into a predetermined category selected from a group of categories comprising at risk, affected (ARA) and at risk unaffected (ARU);

analyze genetic test result data to determine genetic differences between the subjects in the ARA category and subjects in the ARU category; and

identify a target for treating the selected biological condition.

42. (Original) The system of claim 41 wherein the processor combines the numerical scores for affected status and risk status to form a combined numerical score, the processor further classifying of each of the plurality of subjects into a predetermined category being based on the combined numerical scores for affected status and risk status.

43. (Original) The system of claim 41 wherein the medical tests associated with the selected biological condition have varying degrees of relevance in defining the disease characteristics, the processor further assigning relevance weighting factors to the medical tests based on the degree of relevance, the processor determining the affected status based on the weighted medical tests.

44. (Original) The system of claim 41 wherein the processor further generates statistical data related to the affected status and risk status, the processor further classifying of each of the plurality of subjects into a predetermined category

being based on the combined numerical scores for affected status and risk status based on analysis of the statistical data.

45. (Canceled)

46. (Original) The system of claim 41 wherein the processor further classifies each of the plurality of subjects into a predetermined category selected from a group of categories comprising at-risk, affected (ARA), unknown risk, unaffected (URU), and at risk unaffected (ARU).

47. (Previously Presented) The method of claim 1 wherein identifying a target comprises identifying a drug target based on the genetic variations between genetic test results of the group of subjects classified as ARU with the genetic test results of the group of subjects classified as ARA.

48. (Previously Presented) The method of claim 1 wherein identifying a target comprises identifying a diagnostic assay based on the genetic variations between genetic test results of the group of subjects classified as ARU with the genetic test results of the group of subjects classified as ARA.

49. (Currently Amended) The method of claim 1 wherein identifying a target comprises identifying a vaccine component based on the genetic variations between genetic test results of the group of subjects classified as ARU with the genetic test results of the group of subjects classified as ARA.

50. (Currently Amended) The method of claim 1 wherein identifying a target comprises identifying a candidate drug component based on the genetic variations between genetic test results of the group of subjects classified as ARU with the genetic test results of the group of subjects classified as ARA.

51. (Currently Amended) The method of claim 20 wherein identifying a target comprises identifying a candidate drug component-based on the genetic variations between genetic test results of the group of subjects classified as *ARU* with the genetic test results of the group of subjects classified as *ARA*.

52. (Previously Presented) The system of claim 41 wherein the processor is configured to identify a drug target based on the genetic variations between genetic test results of the group of subjects classified as *ARU* with the genetic test results of the group of subjects classified as *ARA*.

53. (Currently Amended) The system of claim 41 wherein the processor is configured to identify a candidate drug component-based on the genetic variations between genetic test results of the group of subjects classified as *ARU* with the genetic test results of the group of subjects classified as *ARA*.

54. (Previously Presented) The system of claim 41 wherein the processor is configured to identify a diagnostic assay based on the genetic variations between genetic test results of the group of subjects classified as *ARU* with the genetic test results of the group of subjects classified as *ARA*.

55. (Currently Amended) The system of claim 41 wherein the processor is configured to identify a vaccine component-based on the genetic variations between genetic test results of the group of subjects classified as *ARU* with the genetic test results of the group of subjects classified as *ARA*.

Please add the following new claims:

56. (New) A computer-implemented method for the classification of a population for evaluation of a selected biological condition, comprising:

defining risk characteristics associated with the selected biological condition;

storing data associated with the defined risk characteristics;

defining affected status indicators for the selected biological condition;

storing data associated with the defined affected status indicators;

using the stored data to classify a study population based on the defined risk characteristics and the defined affected status indicators to thereby classify individual ones of the subjects in the study population as at risk and affected (ARA) by the selected biological condition, the ARA individuals having a risk status indicating the expectation that the individuals are at significant risk for having the selected biological condition at the present time, and an affected status indicating that the ARA individuals are presently affected by the selected biological condition, and to classify individual ones of the subjects in the study population as at risk and unaffected (ARU) by the selected biological condition, the ARU individuals having a risk status indicating the expectation that the individuals are at significant risk for having the selected biological condition at the present time, and an unaffected status indicating that the ARU individuals are presently not affected by the selected biological condition.

57. (New) A computer-implemented method for the classification of a population for evaluation of a selected biological condition, comprising:

selecting a study population to be classified into subpopulations selected from a group of subpopulations comprising:

at risk and affected (ARA), whose members have a risk status indicating the expectation that the members are at significant risk for having the selected biological condition at the present time, and an affected status indicating that the members of the ARA subpopulation are presently affected by the selected biological condition;

at risk and unaffected (ARU) by the selected biological condition, whose members have a risk status indicating the expectation that the members are at significant risk for having the selected biological condition at the present time, and an affected status indicating that the ARU individuals are presently not affected by the selected biological condition, and

unknown risk and unaffected (URU) by the selected biological condition, whose members have an indeterminate risk status for having the selected biological condition at the present time, and an affected status indicating that the URU individuals are presently not affected by the selected biological condition;

the size of the study population being selected so that the number of potential ARU members provides 95% confidence to detect alleles represented at at least 1% frequency in the ARU sub-population; and

based on computer analysis of the data related to the medical histories and the data related to the medical test results, classifying the study population into the ARA, ARU or URU sub-populations to permit evaluation of the selected biological condition by analyzing at least two of the subpopulations.

58. (New) The method of claim 57, further comprising:
performing a computer analysis of genetic data from the ARA sub-population and the ARU sub-population to identify genetic variations therebetween; and
using data related to the identified genetic variations between the ARA sub-population and the ARU sub-population to identify a drug target associated with the selected biological condition.

59. (New) A method for the classification of a population for evaluation of a selected biological condition, comprising:
defining risk characteristics associated with the selected biological condition;

defining affected status indicators for the selected biological condition; classifying a study population based on the defined risk characteristics and the defined affected status indicators to thereby classify individual ones of the subjects in the study population as at risk and affected (ARA) by the selected biological condition, the ARA individuals having a risk status indicating the expectation that the individuals are at significant risk for having the selected biological condition at the present time, and an affected status indicating that the ARA individuals are presently affected by the selected biological condition, and to classify individual ones of the subjects in the study population as at risk and unaffected (ARU) by the selected biological condition, the ARU individuals having a risk status indicating the expectation that the individuals are at significant risk for having the selected biological condition at the present time, and an affected status indicating that the ARU individuals are presently not affected by the selected biological condition, the size of the study population being selected so that the number of potential ARU members provides 95% confidence to detect alleles represented at at least 1% frequency in the ARU sub-population.

60. (New) A computer-implemented method for the classification of a population for evaluation of a selected biological condition, comprising:

defining risk characteristics associated with the selected biological condition;

storing data associated with the defined risk characteristics;

defining affected status indicators for the selected biological condition;

storing data associated with the defined affected status indicators;

using the stored data to classify a study population based on the defined risk characteristics and the defined affected status indicators to thereby classify individual ones of the subjects in the study population as at risk and affected (ARA) by the selected biological condition, the ARA individuals having a risk status indicating that the individuals are expected to be affected by the selected biological condition at the

present time, and an affected status indicating that the ARA individuals are presently affected by the selected biological condition, and to classify individual ones of the subjects in the study population as at risk and unaffected (ARU) by the selected biological condition, the ARU individuals having a risk status indicating that the individuals are expected to be affected by the selected biological condition at the present time, and an affected status indicating that the ARU individuals are presently not affected by the selected biological condition.

61. (New) A computer-implemented method for the identification of a population phenotypically unaffected by a selected biological condition, comprising:

defining risk characteristics associated with the selected biological condition;

storing data associated with the defined risk characteristics;

defining affected status indicators for the selected biological condition;

storing data associated with the defined affected status indicators;

using the stored data to identify individuals as phenotypically affected by the selected biological condition and to identify individuals as phenotypically unaffected by the selected biological condition despite a risk status consistent with risk status associated with individuals identified as phenotypically affected by the selected biological condition.